REMARKS

Claims 1-9 and 11-13 were pending in this application, with Claims 1 and 12 being independent. Claims 1, 2, 9, and 11 have been amended. Claims 12-13 have been cancelled. New independent Claim 14 has been added. No new matter has been added.

ARGUMENTS

Rejections under Section 112¶1

Claim 1 has been amended to clarify the structure of the implant and to clarify the terminology referring to the body vessel (e.g., artery) versus the implant body (now "member"). Among the amendments made are the following:

1. "Vessel" (for example, artery or vein) has been amended to "body vessel". "Wall", "lumen" and "central axis" have been amended to be "vessel wall", "vessel lumen" and "vessel lumen axis", respectively, to better distinguish between the vessel structure and the member structure. "Body" may be generally referred to in the context of a patient's body.

2. The direction of fluid flow within the vessel lumen has been clarified in the preamble.

3. "Basic body" has been amended to "member" to better distinguish the implant body from the human (or other patient) body.

4. "Hollow" has been added to provide antecedent structural basis for a lumen.

5. The structure of the "member" has been clarified by defining it to include a wall having an interior surface and an exterior surface, the interior surface defining a lumen. The implant member lumen and the body vessel lumen are generally co-axial (since, by definition, the tubular or hollow implant body is likely to be implanted within a tubular (or generally similar) shaped body vessel.

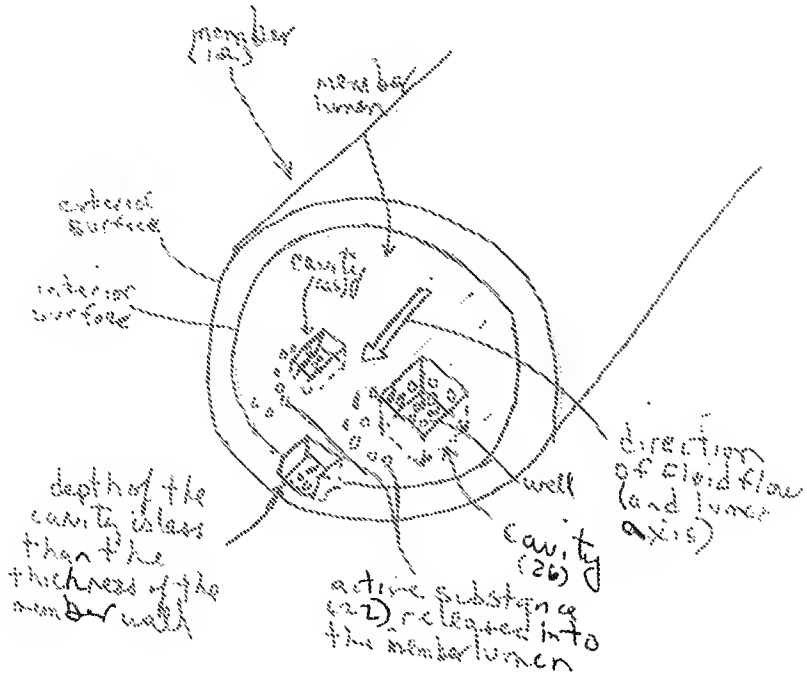
6. The structure of the cavity has been clarified to reflect that it is only in the member wall inner surface and has side walls and bottom portion (see Fig. 2b and ¶¶0030 and

0053). Please note that all references to the specification for support are exemplary only and not necessarily a complete recitation of all instances of such support. "Cavity" has further been clarified to reflect that the active substance which is contained in the cavity is exposed to and can be released into the lumen and not directed toward the exterior surface of the implant. The active substance is contained in the cavities and the non-cavity areas of the interior wall surface are substantially free of the active substance (see ¶0053: "Active substance 22 may be introduced into the cavities 26,...and blowing off the active substance deposits present outside cavities 26.") Support for "cavity" as a recess not fully enclosed by the implant body is at ¶0030.

7. Support for "the member interior wall surface portion not forming the cavity being substantially free of active substance" may be found at ¶0053 (describing the manufacturing process including: "...blowing off the active substance deposits present outside cavities 26.")

Claims 2, 9, and 11 have been amended to reflect the change from "basic body" to "member".

The following rough drawing is provided for the Examiner's convenience in visualizing and matching the terms in the present claims with the part numbers. This drawing corresponds to the exemplary embodiment shown in Fig. 2b; certain elements have been omitted only for simplification to show the elements as amended in Claim 1. Broken lines show the depth of the cavity.



Applicant respectfully traverses the Examiner's characterization of "a basic body lumen" as being new matter (in ¶¶6 and 14 of the Office Action). As noted above, Applicant has amended the claims to address the Section 112 rejections. The "basic body lumen", now "member lumen" is described in the specification at, for example, ¶0043 ("Implant 10 consists of a tubular basic body 12 which is open on its front sides 14 and 16 and through which a body medium is able to flow.") This description of a tube inherently defines a lumen. As such, no new matter has been claimed.

The term "basic body" has been clarified and "hollow body" has been deleted.

Rejection under Section 102(b) over Sirhan et al. ("Sirhan")

Sirhan is cited as teaching a coating on a portion of the body interior surface. The implant of present Claim 1 has an inner surface containing and does not have the surface of the interior wall coated with active substance; rather, the cavities are essentially the only location in which active substance resides (see specification at ¶0053 and see arguments above in #7 in the list of amendments made).

The Examiner states that Sirhan discloses at least one "cavity" which is defined by the spaces between the ring segments 73 and the links 76 (as shown in Fig. 4). This "cavity" is formed by a loop in the serpentine wire and is open on both interior and exterior sides. This structure is a two-dimensional recess, rather than a well. Active substance retained in the recess can be released to the areas proximate to the implant and absorbed by the blood vessel wall tissue, thus reducing the amount of active substance available for transport downstream. In contrast, the cavity 26 of present Claim 1 is defined as having side walls and a bottom portion forming a three-dimensional well. See the specification at ¶0030, referring to Fig. 2b ("recesses, gaps or even drilled holes...which [in this particular embodiment] are not fully enclosed" bracketed material added) and at ¶0053 ("Cavities 26 can be realised in the form of gaps, holes or other geometries"). The cavities, as presently described in Claim 1, are distinguishable over Sirhan's open wire-defined recesses. One of ordinary skill in the art could not adapt the thin wire framework recesses of Sirhan to create a three-dimensional cavity without completely changing the design.

The Examiner further cites Sirhan as disclosing cavities which have their opening facing "toward the vessel lumen axis (Figure 4)". As discussed above, Sirhan's wire loop recesses the Examiner characterizes as cavities are open to both the interior (e.g., toward the blood vessel lumen) and exterior environments (e.g., in contact with the blood vessel wall) in the body vessel, thus allowing active substance to be released in a manner which directs contact and absorption; of the released active substance with the body vessel wall as well as being released toward the body vessel lumen axis. This release of active substance on all sides of the implant, both into the lumen as well as directly toward the body vessel wall, results in more of the active substance being absorbed by the body vessel wall proximate to the implant location and less of the active substance being available for direction downstream.

In contrast to Sirhan, the implant of present Claim 1 recites a structure in which the cavities are only in the interior surface of the member wall and the active substance, when released, is directed generally inwardly toward the lumen axis rather than both inwardly and outwardly toward the body vessel wall. As such, the presently claimed member exterior surface can act as a partial "barrier" to active substance being released toward the body vessel wall. The

claimed structure has the feature of enabling the release of substantially all the active substance into the body vessel lumen and downstream to the area of interest. As discussed in the specification at ¶0004-0007, Regional Drug Delivery, i.e., spatially separating the site of implant implantation and the site to which drug is to be delivered, is a feature of the presently claimed implant. This is achieved by the implant of Claim 1 by the inwardly-opening cavities directing prolonged release of drug into the blood vessel (for example) and the blood carrying the drug downstream. See specification at ¶0011. In contrast, the implant of Sirhan is designed for Local Drug Delivery, i.e., delivery of drug at or proximate to the site of implantation. Sirhan is directed to a drug-eluting structure designed to reduce the incidence of restenosis by directing the elution of drug along the length of the implant structure (or a portion thereof) so that drug is directed primarily to be absorbed by the tissue of the vessel wall in contact with the structure or just beyond the structure, hence Local Drug Delivery. More absorption of drug by the blood vessel wall at the implantation site (desired by Sirhan) means less drug available for flowing downstream to a remote target site (desired for Regional Drug Delivery, as with the presently claimed structure).

Claim 1 is further distinguished from Sirhan in that the noncavity areas of the presently claimed implant are substantially free of active substance. In contrast, there is no disclosure or suggestion in Sirhan that areas not defining cavities are free of coating by the active substance. In fact, Sirhan teaches the converse at ¶0065: "the therapeutic capable agent is disposed adjacent all of the surface of at least one of the abluminal and luminal surfaces..."; "the source may be disposed on all of at least one of the abluminal or luminal surfaces or only on the portions of the cylindrical frame, usually, only on those portions of the ring and/or outer links...".

Accordingly, the presently claimed implant is neither anticipated by nor rendered obvious over Sirhan.

Rejection of Claims 12 and 13 under Section 102(b) based on Ragheb et al. ("Ragheb")

Claims 12 and 13 have been cancelled.

Rejection of Claims 2-8 under Section 103(a) based on Sirhan, and in view of Meyer-Lindenberg et al. ("Meyer-Lindenberg")

Sirhan has been discussed and distinguished above. Meyer-Lindenberg is cited as disclosing the magnesium alloy material. There is no suggestion or motivation in the references for one of ordinary skill in the art to combine the two references to produce the presently claimed implant without undue experimentation. The wire structure of Sirhan, regardless whether made of Sirhan's material or Meyer-Lindenberg's material, could not reasonably be modified to create the implant member structure having the claimed cavity structure. Therefore, the combination of Sirhan and Meyer-Lindenberg do not render the present invention obvious.

New Claim 14 is similar to Claim 1, but instead of at least one cavity open to the lumen there is at least one hollow space being defined as being totally enclosed by the implant body. Support is at ¶0031. The interior surface (including the top portion of the hollow space) of the member degrades over time and exposes the active substance, which is eluted downstream. As with the implant described in Claim 1, the active substance is released into the vessel lumen to be washed downstream, rather than absorbed mainly by the vessel wall which is proximate to the implant.

CONCLUSION

Applicant submits that the present application is in condition for allowance and respectfully requests such action. If the Examiner has any questions that can be answered by telephone, please contact the undersigned attorney of record at the telephone number listed below. It is requested that, if necessary to effect a timely response, this paper be considered a Petition for an Extension of Time sufficient to effect a timely response with the fee for such extensions and shortages in other fees being charged, or any overpayment in fees being credited, to the Account of Barnes & Thornburg LLP, Deposit Account No. **50-4913**.

Respectfully submitted,

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